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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,801	11/29/2005	Antonio Cosme Gomez	932.1336	6905

21831 7590 10/29/2007  
WOLF BLOCK SCHORR AND SOLIS-COHEN LLP  
250 PARK AVENUE  
NEW YORK, NY 10177

EXAMINER
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PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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10/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/558,801	COSME GOMEZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,6,9,12-19,22 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,9,12-19,22 and 26-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 27 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Specifically claim 27 is directed to a method of preventing bacterial or protozoan infection. The broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host. There is no evidence that entry would be prevented, therefore that utility would not be credible.

Claim 27 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed September 14, 2007 have been fully considered but they are not persuasive.

Applicant contends that the use of azithromycin as a preventive treatment is well known in the art. This argument has not been found persuasive since the definition of the terminology "preventive treatment" is not set forth in the specification. Therefore, said terminology encompasses the preventing a single microorganism entry into a host cell. Since there is no evidence that entry would be prevented, the above stated rejection has not been overcome.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 9, 12-17, 22, 26-28, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Asero et al (U.S. Patent No. 6,277,829). Or Khamar et al (WO 02/07736 A1)

Asero disclose the claimed formulation comprising azithromycin and citric acid, wherein the molar ratio of azithromycin to citric acid is about 1:0.67 to 1:1.5 and the pH is adjusted to 5.5-7.6 (column 3, lines 51-57) and having concentration of 10% (column 4, lines 1-2).

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Khamar et al disclose dissolving citric acid in water, adjusting the pH to 4 to 6 and adding azithromycin. Page 4, Example 1). An addition salt comprising azithromycin and citric acid would have been inherently formed from such a process.

Applicant's arguments filed September 14, 2007 have been fully considered but they are not persuasive.

Applicant contends that under conditions disclosed by Asero, azithromycin hydrogen citrate should not be formed. This argument has not been found persuasive since applicant has not presented any evidence that the claimed salt is not present in the composition disclosed by Asero.

Applicant also contends that Khamar does not disclose the isolation of the salt formed. This argument has not been found persuasive since the present are not limited to an isolated azithromycin hydrogen salt but encompass said salt in admixture with any other additional component. Applicant further contends that the conditions disclosed by Khamar would not result in the formation of azithromycin hydrogen citrate. This argument has not been found persuasive since applicant has not presented any evidence that the claimed salt is not present in the composition disclosed by Khamar.

Claims 1, 6 9, 12-19, 22 and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aero et al (U.S. Patent No. 6,277,829) or Khamar et al (WO 02/07736 A1).

Each of Asero et al and Khamar et al discloses combining citric acid and azithromycin but does not disclose isolation of azithromycin hydrogen citrate by crystallization. However, since crystalline azithromycin is well known in the art, such as

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azithromycin dihydrate disclosed by Khamar et al, a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to crystallize citric salt of azithromycin because said salt would have been expected to possess similar properties as known crystalline forms of azithromycin.

Applicant's arguments filed September 14, 2007 have been fully considered but they are not persuasive.

Applicant has not presented any evidence that azithromycin hydrogen citrate is not present in the compositions disclosed by the cited prior art. In the event that the claimed salt is not present, note the claimed compound is identical to the known compound, azithromycin, with the exception that the salt is now claimed. Since salts are generally recognized as having superior solubility properties, in the absence of unexpected result or property, claims to the salt of a known compound are considered obvious over a known compound.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

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